

U.S.S.N. 09/760,046
Filed: January 12, 2001
AMENDMENT AND RESPONSE TO OFFICE ACTION

Remarks

Claims 1, 3, 4, 6-13, 15-26, and 34 are pending. Claims 1, 18, 21, and 23 have been amended. Claim 24 has been canceled. New claim 35 has been added. New claim 35 reinstates previously canceled claim 2. Claim 1 has been amended to specify that the macromolecular material is dissolved in a solvent which is non-solvent for the agent to form a dispersion containing microparticles of agent. Support for this amendment can be found in the specification at least at page 8, lines 14-15, page 13, lines 28-29, and in claim 24 as originally filed. Claims 18, 21, and 23 have been amended to correct their antecedent basis.

Applicants believe that it is proper for the present amendment to be entered since it places the application in condition for allowance. Alternatively, entry of this amendment is proper since it places the claims in better form for appeal, does not raise any new issues, and does not require further consideration or search.

Rejection Under 35 U.S.C. § 102

Claims 1, 3, 7-9, 11-13, 15-17, 19, and 23-26 were rejected under 35 U.S.C. § 102(b) as being anticipated by WO 98/46212 to Shah ("Shah"). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Shah

Shah discloses a method for encapsulating a protein to forming sustained-release microcapsules with a protein core. Shah requires the following steps:

- (1) dissolving a polymer in an organic solvent to form a polymeric solution,

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- (2) adding an active agent to the polymeric solution to form a first emulsion or suspension,
- (3) dispersing the first emulsion or suspension in a continuous phase to form a dispersion,
- (4) adding an excipient to the dispersion,
- (5) freezing the dispersion, and
- (6) lyophilizing the frozen dispersion to remove solvents and produce microparticles containing protein. (see Shah, page 6, lines 7-16)

Thus Shah discloses forming a double emulsion (steps 1 through 3) and freezing the double emulsion (step 5) (see also Figure 1).

The claims, as amended, define a different method than Shah's encapsulation process.

Claim 1, the sole independent claim, requires the following steps:

- (1) dissolving a macromolecular material in an effective amount of a solvent, to form a solution;
- (2) dissolving or dispersing the agent in the solution to form an emulsion and thereby micronize the particles of the agent;
- (3) freezing the emulsion;
- (4) drying by vacuum the emulsion to form solid micronized particles of the agent dispersed in solid macromolecular material; and

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(5) dissolving the macromolecular material in an effective amount of a solvent for the macromolecular material to form a dispersion of microparticles in the solvent, wherein the solvent is a non-solvent for the agent.

Claim 1 requires forming an emulsion containing (i) a macromolecular material, (ii) an organic solvent, and (iii) a protein, peptide or drug agent (steps 1 and 2) and then freezing *this emulsion* (step 3). Thus, the emulsion formed in step 2 is not a double emulsion. In contrast, Shah does not disclose forming a single emulsion and freezing the emulsion, as required by claim 1.

Further, Shah does not disclose the final step required by claim 1. Following lyophilization (step 4), the macromolecular material is dissolved in a solvent that is a non-solvent for the agent. Thus, claim 1 does not define a method for encapsulating microparticles of an agent. Dependent claims 3, 16-22, 24, and 25 define encapsulation steps which may be used following the micronization process defined by claim 1. In contrast, Shah forms a double emulsion and lyophilizes the double emulsion to encapsulate proteins. Shah does not describe an additional step of dissolving the encapsulating materials. Thus, Shah does not disclose every element of claim 1 and its dependent claims. Therefore the claims, as amended, are novel in view of Shah.

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AMENDMENT AND RESPONSE TO OFFICE ACTION**Rejection Under 35 U.S.C. § 103**

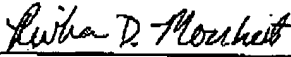
Claims 1, 3, 4, 6-13, 15-26, and 34 were rejected under 35 U.S.C. § 103(a) as being obvious over Shah. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

As noted above, Shah discloses a process for encapsulating proteins. This process involves different steps than the claimed method. There is no suggestion in Shah to modify its process so that it can form a single emulsion which is frozen, as required by the claims. Additionally, there is not suggestion in Shah to modify its methods to include a dissolution step following the lyophilization step. Such a step would remove the polymer that encapsulates the active agent; and thereby defeat the purpose of Shah's encapsulation process. Thus the claims as amended are non-obvious over Shah.

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Allowance of claims 1, 3, 4, 6-13, 15-23, 25, 26, 34, and 35, as amended, is respectfully solicited.

Respectfully submitted,


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Certificate of Facsimile Transmission

I hereby certify that this Amendment and Response to Office Action, and any documents referred to as attached therein are being facsimile transmitted on this date, February 18, 2004, to the Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.


Pam Turnbough

Date: February 18, 2004